PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A23L 1/305, 1/30

A1

(11) International Publication Number: WO 97/16079

(43) International Publication Date: 9 May 1997 (09.05.97)

(21) International Application Number: PCT/EP96/04514

(22) International Filing Date: 15 October 1996 (15.10.96)

(30) Priority Data:
08/549,559 27 October 1995 (27.10.95) US

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(81) Designated States: AU, BR, CA, CN, CZ, FI, HU, JP, KR, MX, NO, NZ, PL, RO, RU, SG, TR, Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: NUTRITIONAL SUPPORT OF PAEDIATRIC PATIENTS

(57) Abstract

An enteral composition for paediatric patients. The composition is made up of a protein source, a carbohydrate source and a lipid source. The protein source provides 10 % to 14 % of the total calories and is in the form of casein and whey. The lipid source is a mixture of medium and long chain triglycerides of which at least 20 % are medium chain triglycerides. The composition may be used for providing nutrition to a paediatric patient; especially patients suffering from cerebral palsy or recovering from trauma, burns or surgery and having moderate needs for tissue repair.

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Nutritional Support of Paediatric Patients

This invention relates to an enteral composition for use in the treatment and nutritional support of paediatric patients and the methods for the treatment and nutritional support of paediatric patients.

The measurement of diet adequacy in patients, especially paediatric patients, is difficult. Increases in a child's weight and length only grossly reflect nutritional progress. The daily requirements for adequate nutrition are especially significant for the growing child compared with the adult. The relative need for protein, vitamins and minerals remains constant and is greater than that of adults. Moreover, requirements for various vitamins depend on the intake of calories, protein, fat, carbohydrate and specific amino acids.

While the nutritional needs of the paediatric patient differ from adult patients, in health care settings, adult nutritional formulas are the primary form of elemental nutrition currently being used for children. Naturally, adult formulas do no take into effect the known nutritional needs of the paediatric patient. Adult nutritional products must be diluted to decrease concentrations of, for example, protein, sodium, chloride and the renal solute load to levels recommended for children. This dilution reduces the concentrations of other needed nutrients that are often already in concentrations too low for children (i.e. calcium and phosphorous). Thus, providing a nutritional formula designed specifically for children would be advantageous.

A whole protein enteral formula sold under the trademark PEDIASURE® is currently available from Ross Laboratories for nutritional therapy of paediatric patients. PEDIASURE® contains 12% protein, 44% carbohydrates, and 44% fat. The whole protein formula has a protein composition of 82% casein and 18% whey.

Although PEDIASURE® is formulated for children, it is designed to provide nutrition for a limited population, namely children of 1 to 6 years old. As a result thereof, while PEDIASURE® may meet the Recommended Daily Allowances (RDAs), set by the National Academy of Sciences-National Research Council (NAS-NRC), for children 1 to 6 years old in 1000 calories, it requires 1300 calories to meet the RDA of children ages 7 to 10 years.

Therefore, a need exists for a nutritional formula designed to meet the nutritional needs of a larger base of paediatric patients as well as paediatric patients recovering from trauma, post-surgical and moderate traumatic injuries and burns.

Accordingly, in one aspect, this invention provides an enteral composition suitable for paediatric patients. The enteral composition comprises: a protein source providing 10% to 14% of the total calories, the protein source comprising casein and whey and providing relatively rapid gastric emptying and reduced gastric reflux; a carbohydrate source; and a lipid source comprising a mixture of medium and long chain triglycerides, at least 20% of the lipid source being medium chain triglycerides.

Preferably, the protein source comprises casein and whey, most preferably about 50% casein and 50% whey, to improve the rate of gastric emptying and reduce the incidence of gastric reflux as compared to diets containing only casein or predominantly casein. The protein preferably also provides a rich source of cysteine; for example the composition may contain about 0.15% of calories as cysteine (about 350 mg/1000 calories).

The carbohydrate source preferably provides about 40% to about 60% of the total calories of the composition. The carbohydrate source is maltodextrin, corn starch or sucrose, and mixtures thereof.

The lipid source preferably provides about 30% to about 40% of the total calories of the composition. The long chain triglycerides are preferably selected from soy oil, canola oil, residual milk fat, and soy lecithin. Preferably the lipid source has an omega-3 to omega-6 fatty acid ratio of approximately 4:1 to 6:1.

The composition may further includes at least 100% of the NAS-NRC RDA for children of all vitamins and minerals per 100 kcals.

In another aspect, this invention provides a method for providing nutrition to a paediatric patient. The method comprises the step of administering to the patient a therapeutically effective amount of an enteral composition comprising: a protein source comprising about 10% to about 14% of the total calories; a carbohydrate source; and a lipid source comprising a mixture of medium and long chain triglycerides; the lipid source having an omega-3 to omega-6 fatty acid ratio of about 4:1 to about 6:1 and the medium chain triglycerides comprising at least 25% of the lipid source.

In another aspect, this invention provides a method for providing nutrition to a paediatric patient with moderate needs for tissue repair recovering from trauma, burns or surgery or suffering from cerebral palsy. The method comprises the step of administering to the patient a therapeutically effective amount of an enteral composition comprising: a cysteine-rich protein source which provides about 10% to about 14% of the total calories of the composition; a carbohydrate source; and a

lipid source comprising a mixture of medium and long chain triglycerides of which the medium chain triglycerides make up at least 25%.

In another aspect, this invention provides the use of a lipid source in the form of a mixture of medium chain triglycerides and long chain triglycerides of which the medium chain triglycerides comprises at least about 25% and having an omega-3 to omega-6 fatty acid ratio of about 4:1 to about 6:1, in the preparation of an enteral composition for providing nutrition to a paediatric patient.

In another aspect, this invention provides the use of a cysteine-rich protein source and a lipid source in the form of a mixture of medium chain triglycerides and long chain triglycerides of which the medium chain triglycerides comprises at least about 25%, in the preparation of an enteral composition for providing nutrition to a paediatric patient suffering from cerebral palsy or recovering from trauma, burns or surgery and having moderate needs for tissue repair.

The invention has the advantage that it provides enteral composition that is ready-to-use, nutritionally complete, and contains proteins, lipids, carbohydrates and vitamins and minerals in proportions appropriate for children ages 1-10 years.

Moreover, the enteral composition has optimal tolerance and absorption in children ages 1-10 years.

Also the protein source in a concentration that is adequate to support growth and moderate needs for tissue repair without imposing an undue nitrogen burden on renal function.

Embodiments of the invention are now described by way of example only.

Nutritional support of hospitalised children requires prevention, recognition, and treatment of the nutritional depletion that may occur with illness. The goals of nutritional support include stabilising metabolic state, maintaining body mass, and/or facilitating growth and promoting tissue repair in the presence of disease and/or trauma. While diseases relating to nutritional deficiency are unusual in first world countries, other disease states exist that alter intake, absorption or metabolism. Certain health conditions can impair the nutrient absorption and/or reduce gastrointestinal tolerance for diets which are based on whole proteins, long-chain fatty acids and/or complex carbohydrates. Hence there is a need for an enteral composition which is able to provide adequate nutrition to children.

The enteral composition which is suitable for supplying nutrition to paediatric patients is made up of a protein source, a carbohydrate source, and a lipid source.

The protein source provides about 10% to 14% of the total calories of the composition. For example, the protein source may provide about 12% of the total calories of the composition. This protein concentration is adequate to support growth and moderate needs for tissue repair without imposing an undue nitrogen burden on renal function for children ages 1 to 10 years.

The protein source preferably comprises a mixture of casein and whey proteins. The whey protein may be present in whole or in hydrolyzed form. Preferably, the protein source comprises at least about 50% whey protein; for example in the form of hydrolyzed whey. This protein source reduces the incidence of gastric reflux because gastric emptying is faster than with diets containing casein or predominantly casein. Also, whey protein serves as a rich source of the amino acid cysteine. Cysteine is a limiting amino acid for the formation of glutathione, and glutathione needs may be higher in children with infectious or inflammatory conditions. Preferably, the enteral composition contains approximately 0.15% of calories as cysteine (approximately 350 mg per 1000 calories).

The carbohydrate source provides about 40% to about 60% of the caloric content of the composition. For example, the carbohydrate source may provide about 51% of the caloric content of the composition. A number of carbohydrates can be used including maltodextrin, hydrolyzed corn starch and/or sucrose.

The lipid source includes a mixture of medium chain triglycerides (MCT) and long chain triglycerides (LCT). Preferably the lipid source provides about 30% to about 40% of the caloric content of the composition. For example, the lipid source may provide about 37% of the caloric content of the composition. The lipid profile is designed to meet essential fatty acid (omega-3 and omega-6) needs of children, and for example comprises about 12.6% of essential fatty acids based on total calories.

The lipid source preferably includes at least about 20 to about 30% of medium chain triglycerides. For example, MCTs may make up at least about 25% of the lipid source.

Suitable sources of long chain triglycerides are canola oil, soy oil, residual milk fat, and soy lecithin. The lipid profile of the enteral composition is preferably designed to have a polyunsaturated fatty acid omega-6 (n-6) to omega-3 (n-3) ratio of about 4:1 to about 6:1. For example, the n-6 to n-3 fatty acid ratio may be about 5:1. Both the omega-6 and omega-3 fatty acids are provided in sufficient quantity to meet tissue growth maintenance needs. To this end, the source of omega-6 fatty

acids preferably provides about 4 to about 12% of the total calories. The omega-3 fatty acid source is preferably present in the range of approximately 0.8-3.0% of the total calories. In addition to the absorption/tolerance benefits of a moderate LCT content, the enteral composition less likely to be immunosuppressive due to the low percentage of omega-6 fatty acids.

By way of example, and not limitation, an example of a suitable lipid profile that may be used in the enteral composition is as follows:

Lipid Profile (42.0 grams/litre)

COMPONENT	% of Lipids	Grams/Litre
C6:0	0.6	0.3
C8:0	14.0	5.9
C10:0	6.7	2.8
C12:0	0.3	0.1
C14:0	0.4	0.2
C16:0	6.4	2.7
C18:0	2.2	0.9
C20:0	0.5	0.2
TOTAL SAT	**31.1**	**13.1**
C16:1	0.4	0.2
C18:1	24.1	10.1
C20:1	0.3	0.1
TOTAL MONO	**24.8**	**10.4**
C18:2 n6	27.8	11.7
C18:3 n3	5.7	2.35
TOTAL POLY	**33.5**	**14.05**
TOTAL, FA'S	**89.4**	**37.55**
NON-FA'S	**10.6**	**4.45**
TOTAL, ALL	**100.0**	**42.0**

Where "FA" means fatty acid, and "Sat" means saturated.

P/S Ratio = 1.1; (Saturated includes MCT)

N6 = 27.8% of fat (22.7 g/L) 10.5% of total calories

N3 = 5.7% of fat (2.35 g/L) 2.1% of total calories

N3 to N6 Ratio = 5.0:1.

The lipid source may be made up as follows:

FAT SOURCE	% BY WT	% TOTAL KCAL
MCT	25%	8.7&
CANOLA	24%	9.1%
SOY	43%	16.2%
MILK*	3%	1.1%
SOY LECITHIN	5%	1.9%
TOTAL	100%	37.0

*Residual milk fat (with the casein and whey protein) contributes to the total lipid content

The enteral composition preferably includes a specialised vitamin and mineral profile. In particular, the composition includes a source of vitamins and minerals providing at least 100% of the NAS-NRC Recommended Daily Allowance for children. The vitamin and mineral requirements are met in 1000 kcal per day because this intake is practical, achievable and easily tolerated by children ages 1-10 years, even though it is somewhat less than healthy children normally eat. Unlike prior compositions, the enteral composition meets NAS-NRC RDAs for children ages 1-10 years in 1000 calories. The high vitamin and mineral concentration of the enteral composition is of practical benefit because typical feeding regimens (e.g. 50 ml/hour for 20 hours/day) will meet all needs. However, none of the vitamin or mineral concentrations are so high that there is any risk of approaching toxic levels, even at 2000-2500 kcal per day.

The enteral composition may include a source of beta-carotene. Beta-carotene, formerly considered only as a precursor to vitamin A, is an important nutrient with anti-oxidant properties. For example, the composition may include about 0.5 to about 2.0 mg of beta-carotene per 1000 calories. This amount of beta-carotene is sufficient to maintain plasma beta-carotene concentration in the paediatric patient.

The enteral composition may further include certain electrolyte concentrations. The electrolyte concentrations are set to meet needs without providing an undue renal solute burden on kidney function. To this end, sodium is preferably present in a range of about 420 to about 500 mg/L, potassium is

preferably present in a range of about 1260 to about 1380 mg/L and chloride is preferably present in a range of about 1040 to about 1120 mg/L. The renal solute load is, for example, present in a range of about 200 to about 210 Mosm. In a preferred example, the electrolyte concentrations are as follows: sodium is present at about 460 mg/L; potassium is present at about 1320 mg/L; chloride is present at about 1080 mg/L; and the renal solute load is at about 205 Mosm.

The enteral composition is in the form of a ready-to-use enteral formulation. The composition can be used as a supplement or for total enteral nutritional support. The composition can be tube-fed to a patient, or fed by having the patient drink it. Preferably, the caloric density of the composition is 1.0 kcal/ml. Various flavorants, fibres and other additives may also be present.

The enteral composition may be used for providing nutrition to paediatric patients of ages of 1 to 10 years. Likewise, the composition can be used for providing nutrition to a paediatric patient recovering from surgery, burns or trauma. The diet utilises a significant amount of whey protein, medium chain triglycerides and maltodextrin to enhance absorption and reduce intolerance.

By way of example, and not limitation, suitable compositions that may be used are as follows:

Examples 1 - 2

The enteral nutritional compositions comprise the following ingredients: protein: casein and whey; carbohydrate: maltodextrin and sucrose; lipid: canola oil, soy oil, coconut oil (MCT), residual milk fat, soy lecithin; water; vitamin A (retinol); beta-carotene; vitamin D, vitamin E; vitamin K; vitamin C; thiamine B_1; riboflavin B_2; niacin; vitamin B_6; folic acid; pantothenic acid; vitamin B_{12}; biotin; choline; taurine; L-carnitine; inositol; calcium; phosphorus; magnesium; zinc; iron; copper; manganese; iodine; sodium; potassium; chloride; chromium; molybdenum; and selenium.

The enteral of example 1 includes dietary fibre while that of example 2 does not.

The composition have the following nutrient composition (per 1000 calories):

Paediatric Enteral Nutritional Compositions

COMPOSITION (Per Litre)	UNITS	Example 1	Example 2
Cal. Density	Kcal/ml	1.0	1.0
Cals./Can	Calories	250	250
PROTEIN	g/L (% Kcal)	30.0 (12%)	30.0 (12%)
Casein		50%	50%
Whey		50%	50%
CARBOHYDRATE	g/L (% Kcal)	127.5 (51%)	127.5 (51%)
Maltodextrin		66%	66%
Sucrose		34%	34%
FIBER	g/L	0.0	6.0
LACTOSE CONTENT	g/L	1.5	1.5
FAT	g/L (% Kcal)	42.0 (37%)	42.0 (37%)
% by weight			
Soy oil		43%	25%
MCT		25%	25%
Canola oil		24%	24%
Soy Lecithin		5%	5%
Residual milk fat		3%	3%
MCT	g/L (% Kcal)	10.5 (8.7%)	10.5 (8.7%)
Linolenic (N6)		11.7 10.5%)	11.7 (10.5%)
Linoleic (N3)		2.35 (2.1%)	2.35 (2.1%)
N6:N3 ratio		5.0:1	5.0:1
OSMOLALITY	MOSM	350	350
RENAL SOLUTE LOAD	MOSM/L	205	205
MCT:LCT RATIO		25:75	25:75
volume to meet or exceed NAS-NRC RDA		1.0 L	1.0 L
DENSITY	g/ml	1.057	1.060
WATER	ml/L	850 (85%)	840 (84%)
CAL/gN	Ratio	210:1	210:1
NPC/gN	Ratio	185:1	185:1

Examples 3-4

The enteral compositions may be provided in storage stable, ready to use, liquid form in cans or in retort processed, screw-topped containers. Examples 3-4 show the formulations for 250 ml cans and one litre containers with respect to NAS-NRC recommended dietary allowances for children 7-10 years of age as follows:

Paediatric Nutritional Formulations
in 250 ml and 1 L Containers

Enteral composition	Units	NAS-RC*	Amount per 250ml	%NAS-NRC	Amount per Litre	%NAS-NRC
Calories	Kcal	----	250	**	1000	**
Protein	g	28.0	7.5	27	30.0	107
Carbohydrate	g	----	31.9	**	127.5	**
Fat	g	----	10.5	**	42.0	**
Water	ml	----	212	**	850	**
Vitamin A***	I.U.	2330	600	26	2400	103
β-carotene	mg	**	0.25	**	1.0	**
Vitamin D	I.U.	400	140	35	560	140
Vitamin E	I.U.	7	7	100	28	400
Vitamin K	µg	**	7.5	**	30	**
Vitamin C	mg	45	25	55	100	220
Thiamine B_1	mg	1.0	0.6	60	2.4	240
Riboflavin B_2	mg	1.2	0.5	42	2.0	167
Niacin	mg	13	5	38	20	154
Vitamin B_6	mg	1.4	0.6	43	2.4	171
Folic Acid	µg	100	100	100	400	400
Pantoth. Acid	mg	**	2.5	**	10	**
Vitamin B_{12}	µg	1.4	1.5	107	6	428
Biotin	µg	**	75	**	300	**
Choline	mg	**	75	**	300	**
Taurine	mg	**	20	**	80	**
L-Carnitine	mg	**	10	**	40	**
Inositol	mg	**	20	**	80	**

Calcium	mg	800	250	31	1000	125
Phosphorus	mg	800	200	25	800	100
Magnesium	mg	170	50	29	200	118
Zinc	mg	10	3.8	38	15	150
Iron	mg	10	3.5	35	14	140
Copper	mg	**	0.25	**	1.0	**
Manganese	mg	**	0.4	**	1.5	**
Iodine	µg	120	30	25	120	100
Sodium	mg	**	115	**	460	**
Potassium	mg	**	330	**	1320	**
Chloride	mg	**	270	**	1080	**
Chromium	µg	**	7.5	**	30	**
Molybdenum	µg	**	7.5	**	30	**
Selenium	µg	30	7.5	25	30	100

** NAS-NRC RDA not established

*** 26% from Vit. A plus a max. of 416 I.U. from conversion of beta-carotene (Total=44% NAS-NRC RDA)

Example 5

Another enteral composition is shown in the following Example 5. The following table shows a comparison of the composition of Example 5 with the NAS-NRC RDAs and with a prior paediatric formulation, PEDIASURE® available from Ross Laboratories, as follows:

Comparison of Composition of Example 5 with PEDIASURE®
and NAS-NRC RDAs (Per 1000 Calories)

			NAS-NRC RDAs			
Nutrient composition	Units	Pediasure®	1-3 Yrs	4-6 Yrs	7-10 Yrs	Example 5
CAL. Density	Kcal/ ml	1.0	**	**	**	1.0
Protein	g (%)	30.0 (12%)	16	24	28	30.0 (12%)
Casein		82%				50%
Whey		18%				50%
Carbohydrate	g (%)	109.7 (44%)	**	**	**	127.5 (51%)
FAT	g %)	49.7 (44%)	**	**	**	42.0 (37%)
Safflower Oil		50%				--
Canola Oil		--				24%
Soy Oil		30%				43%
MCT		20%				25%
Residual Milk Fat		--				3%
Soy Lecithin		5%				5%
N6:N3 Ratio		9:1				5:1
Fibre	g	5.0	**	**	**	6.0 or 0.0
Water	ml	844	**	**	**	840 or 850
Vitamin A (retinol)	IU	2570	1325	1665	2330	2400
Beta-carotene	mg	0	**	**	**	1.0
Vitamin D	IU	510	400	400	400	560
Vitamin E	IU	23	6	7	7	28
Vitamin K	µg	38	**	**	**	30
Vitamin C	mg	100	40	45	45	100
Thiamine B_1	mg	2.7	0.7	0.9	1.0	2.4
Riboflavin B_2	mg	2.1	0.8	1.1	1.2	2.0
Niacin	mg	17	9	12	13	20
Vitamin B_6	mg	2.6	1.0	1.1	1.4	2.4
Folic acid	µg	370	50	75	100	400

Pantoth. acid	mg	10	**	**	**	10
Vitamin b_{12}	µg	6	0.7	1.0	1.4	6
Biotin	µg	320	**	**	**	300
Choline	mg	300	**	**	**	300
Taurine	mg	72	**	**	**	80
L-carnitine	mg	17	**	**	**	40
Inositol	mg	80	**	**	**	80
Calcium	mg	970	800	800	800	1000
Phosphorus	mg	800	800	800	800	800
Ca:P	Wt	1.21:1	1.0:1	1.0:1	1.0:1	1.25:1
Magnesium	mg	200	80	120	170	200
Zinc	mg	12	10	10	10	15
Iron	mg	14	10	10	10	14
Copper	mg	1.0	**	**	**	1.0
Manganese	mg	2.5	**	**	**	1.5
Iodine	µg	97	70	90	120	120
Sodium	mg	380	**	**	**	460
Potassium	mg	1310	**	**	**	1320
Chloride	mg	1010	**	**	**	1080
Na:K	Molar	0.49:1	**	**	**	0.59:1
(Na+K)/Cl	Molar	1.75	**	**	**	1.71
Chromium	µg	30	**	**	**	30
Molybdenum	µg	36	**	**	**	30
Selenium	µg	23	20	20	30	30

** NAS-NRC RDA not established.

It will be understood that various modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

Claims

1. An enteral composition for paediatric patients comprising:

a protein source providing 10% to 14% of the total calories and comprising casein and whey in whole or hydrolysed form;

a carbohydrate source; and

a lipid source comprising a mixture of medium and long chain triglycerides, at least 20% of the lipid source being medium chain triglycerides.

2. A composition of Claim 1 in which the protein source comprises about 50% casein and about 50% intact or hydrolyzed whey.

3. A composition of Claim 1 in which the carbohydrate component is sucrose, maltodextrin or corn starch, and mixtures thereof.

4. A composition of Claim 1 in which the long chain triglycerides are selected from soy oil, canola oil, residual milk fat, and soy lecithin.

5. A composition of Claim 1 in which the lipid source has an omega-6 to omega-3 fatty acid ratio of 4:1 to 6:1.

6. A composition of Claim 5 in which the omega-6 fatty acids provide about 10.5% of total calories and the omega-3 fatty acids provide about 2.1% of total calories.

7. A composition of Claim 1 further comprising at least 100% of the NAS-NRC RDA of all vitamins and minerals in 1000 calories.

8. A composition of any of claims 1 to 7 in which the protein source provides cysteine in an amount of about 0.15% of calories of the composition.

9. The use of a lipid source in the form of a mixture of medium chain triglycerides and long chain triglycerides of which the medium chain triglycerides comprises at least about 25% and having an omega-3 to omega-6 fatty acid ratio of about 4:1 to about 6:1, in the preparation of an enteral composition for providing nutrition to a paediatric patient.

10. The use of a cysteine-rich protein source and a lipid source in the form of a mixture of medium chain triglycerides and long chain triglycerides of which the medium chain triglycerides comprises at least about 25%, in the preparation of an enteral composition for providing nutrition to a paediatric patient suffering from cerebral palsy or recovering from trauma, burns or surgery and having moderate needs for tissue repair.

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/EP 96/04514

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A23L1/305 A23L1/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 340 603 A (M.J.NEYLAN ET AL.) 23 August 1994 see table 10 see column 21, line 55-63 see claims	1-10
X	EP 0 486 425 A (SANDOZ NUTRITION) 20 May 1992 see page 2, line 23-56; claims; example 2	1-10
A	WO 94 01001 A (DANOCHEMO) 20 January 1994 see claims	1,9
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[X] Further documents are listed in the continuation of box C.

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12 December 1996	20. 12. 96

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European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	VAN MOER, A

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International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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